

§ 520.310

(2) Nos. 000115, 000859, 055529, and 062250 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

(c) [Reserved]

(d) *Conditions of use in dogs*(1) *Amount*. 2 mg per pound (lb) of body weight once daily or 1 mg/lb twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Indications for use*. For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

(3) *Limitations*. Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 66581, Dec. 18, 1996, as amended at 64 FR 32181, June 16, 1999; 66 FR 63165, Dec. 5, 2001; 67 FR 6866, Feb. 14, 2002; 67 FR 65038, Oct. 23, 2002; 67 FR 65697, Oct. 28, 2002; 70 FR 30626, May 27, 2005; 71 FR 51995, Sept. 1, 2006; 72 FR 68478, Dec. 5, 2007; 74 FR 21768, May 11, 2009; 78 FR 52853, Aug. 27, 2013; 78 FR 66264, Nov. 5, 2013]

§ 520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications*. Each tablet contains 10 milligrams of 5st caramiphen ethanedisulfonate and 80 milligrams of ammonium chloride.¹

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*(1) *Amount*. One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.¹

(2) *Indications for use*. For relief of cough.¹

[43 FR 55385, Nov. 28, 1978]

§ 520.312 Carnidazole tablets.

(a) *Specifications*. Each tablet contains 10 milligrams of carnidazole.

(b) *Sponsor*. See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*(1) *Amount*. Adult pigeons: 1 tablet (10 milligrams); newly weaned pigeons: ½ tablet (5 milligrams).

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

21 CFR Ch. I (4–1–14 Edition)

(2) *Indications for use*. For treating trichomoniasis (canker) in ornamental and homing pigeons.

(3) *Limitations*. Not for use in pigeons intended for human food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism or when severely ill birds do not respond to treatment.

[54 FR 32336, Aug. 7, 1989]

§ 520.314 Cefadroxil.

(a) *Specifications*(1) Each tablet contains 50, 100, or 200 milligrams (mg) or 1 gram of cefadroxil.

(2) Each milliliter of suspension constituted from powder contains 50 mg of cefadroxil.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—

(1) *Amount*—(i) *Dogs*. Administer 10 mg per pound (lb) body weight twice daily orally.

(ii) *Cats*. Administer 10 mg/lb body weight once daily orally.

(2) *Indications for use*—(i) *Dogs*. For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus*. For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *S. aureus*.

(ii) *Cats*. For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *S. aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 10165, Mar. 5, 2010]

§ 520.370 Cefpodoxime tablets.

(a) *Specifications*. Each tablet contains cefpodoxime proxetil equivalent to 100 or 200 milligrams (mg) cefpodoxime.

(b) *Sponsors*. See Nos. 000009 and 026637 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*(1) *Amount*. 5 to 10 mg per kilogram (2.3 to 4.5 mg per pound) body weight daily for 5 to 7

Food and Drug Administration, HHS

§ 520.390c

days, or for 2 to 3 days beyond the cessation of clinical signs, up to a maximum of 28 days.

(2) *Indications for use.* For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius*, *S. aureus*, *Streptococcus canis* (group G, -hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 52815, Aug. 30, 2004, as amended at 78 FR 5714, Jan. 28, 2013]

§ 520.376 Cephalixin.

(a) *Specifications.* Each chewable tablet contains 75, 150, 300, or 600 milligrams (mg) cephalixin.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 22 mg per kilogram of body weight twice daily for 28 days.

(ii) *Indications for use.* For the treatment of secondary superficial bacterial pyoderma in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[77 FR 47512, Aug. 9, 2012]

§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a) *Specifications.* Each tablet contains 50, 100, 250, or 500 milligrams (mg); 1 or 2.5 grams (g) of chloramphenicol.

(b) *Sponsors.* See § 510.600(c) of this chapter:

(1) For use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section:

(i) No. 054628 for 100-, 250-, and 500-mg; and 1- and 2.5-g tablets;

(ii) No. 000856 for 100-, 250-, and 500-mg tablets;

(iii) No. 000069 for 250-mg tablets.

(2) For use as in paragraphs (c)(1), (c)(2)(ii), and (c)(3) of this section:

(i) No. 061623 for 50-, 100-, 250-, and 500-mg; and 1-g tablets;

(ii) [Reserved]

(c) *Conditions of use in dogs*(1) *Amount.* Administer 25 mg per pound of body weight by mouth every 6 hours.

(2) *Indications for use*—(i) For the treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(ii) For the treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[77 FR 4896, Feb. 1, 2012, as amended at 78 FR 21059, Apr. 9, 2013]

§ 520.390b Chloramphenicol capsules.

(a) *Specifications.* Each capsule contains 50, 100, 250, or 500 milligrams (mg) chloramphenicol.

(b) *Sponsors.* See Nos. 000069 and 050057 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Special considerations.* Federal law prohibits the extralabel use of this product in food-producing animals.

(d) *Conditions of use in dogs*(1) *Amount.* 25 mg per pound of body weight every 6 hours.

(2) *Indications for use.* For treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 75398, Dec. 20, 2005, as amended at 73 FR 18442, Apr. 4, 2008; 75 FR 55676, Sept. 14, 2010]

§ 520.390c Chloramphenicol palmitate oral suspension.

(a) *Specifications.* Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.